



BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2022-0016]

Notice of Withdrawal of Select Agent Regulatory Exclusions for Two Strains of African Swine Fever Virus

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of withdrawal of select agent regulatory exclusions.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has withdrawn the select agent regulatory exclusions for two African swine fever virus strains, ASFV-G-ΔMGF and ASFV-G-Δ9GL/ΔMGF. Possession, use, and transfer of these strains must now comply with APHIS' select agent and toxin regulations. APHIS withdrew the select agent regulatory exclusions for these strains because it has evaluated new information and determined that they have the potential to pose a severe threat to animal health or animal products.

DATES: As of January 7, 2022, the subject select agent exclusions were withdrawn.

FOR FURTHER INFORMATION CONTACT: Dr. Randy Capsel, Science Officer, Division of Agricultural Select Agents and Toxins, Emergency and Regulatory Compliance Services, Animal and Plant Health Inspection Service, 4700 River Road, Riverdale, Maryland 20737; Telephone: (301) 851-3402; email: Randy.T.Capsel@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401, referred to below as the Act) provides for the regulation of certain biological agents and toxins that have the

potential to pose a severe threat to animal and plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within the U.S. Department of Agriculture.

In accordance with the Act, APHIS promulgated the select agent and toxin regulations found in 7 CFR part 331 and 9 CFR part 121. Paragraph (e) in § 121.3 states that an attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or modified toxin does not pose a severe threat to animal health or animal products.

African swine fever virus (ASFV) is listed as a select agent in § 121.3(b) of the select agent and toxin regulations. APHIS approved the initial select agent regulatory exclusions of two ASFV strains, ASFV-G-ΔMGF and ASFV-G-Δ9GL/ΔMGF, based on applications submitted in accordance with the select agent and toxin regulations and with review and recommendations from the Agriculture Interagency Select Agents and Toxins Technical Advisory Committee (Ag-ISATTAC) at meetings on January 27, 2020, and April 8, 2021. Pursuant to § 121.3(e)(1), APHIS listed the exclusions on the National Select Agent Registry website at <https://www.selectagents.gov>.

On January 7, 2022, APHIS withdrew the previously approved select agent regulatory exclusions for the ASFV-G-ΔMGF and ASFV-G-Δ9GL/ΔMGF strains and removed them from the list on the National Select Agent Registry website. In addition, APHIS notified all entities that were known to have the previously excluded ASFV strains that possession, use, and transfer of these ASFV strains must now comply with the select agent and toxin regulations in part 121. APHIS based the decision to withdraw the exclusions on newly acquired information regarding safety and genome instability potentially leading to reversion of virulence that was either unavailable or not provided to either APHIS or Ag-ISATTAC during either the January 2020 or April 2021 discussions for regulatory exclusion. More specifically, among other sources, two

journal articles published in 2020 and 2021 from China's Harbin Veterinary Research Institute identified instability within the MGF genome segments.

With the publication of this notice, we are informing the public that we withdrew the previously approved select agent regulatory exclusions for the ASFV-G- Δ MGF and ASFV-G- Δ 9GL/ Δ MGF strains, effective on January 7, 2022, and that the possession, use, and transfer of these ASFV strains must now comply with the select agent and toxin regulations in part 121. This notice serves as an official record and public notification of these actions.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this action as not a major rule, as defined by 5 U.S.C. 804(2).

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 13th day of October 2022.

Anthony Shea,

Administrator, Animal and Plant Health Inspection Service.